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Research

A formulation of floating tablets of ofloxacin with different grades of hydroxy propyl methyl cellulose polymer

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Abstract

Formulation and evaluation of floating tablets of Ofloxacin. In the present study the formulations were prepared by direct compression method using different proportions of HPMC K4M, HPMC K15M, and HPMC K100M as Swellable polymers. Sodium bicarbonate is used as buoyancy-imparting agent. The prepared formulations were evaluated for different parameters during its Pre-compression and Post-compression stages. The release characteristics of the formulations were studied in *in-vitro* conditions. The *in-vitro* dissolution study of formulation F8 was 99.34 % within 12 h for good release and was fitted to kinetics of drug release for R2 value of Higuchi release mechanism model is 0.964. As an extension of this work for formulation F8, bioavailability, pharmacokinetic, and *in-vivo* studies can be done in future to develop as suitable candidate for a novel drug delivery system.

Keywords: Ofloxacin, HPMC K4M, HPMC K15M and HPMC K100M, Floating Tablets.

INTRODUCTION

Oral delivery of drugs is the most preferable route of drug delivery. Oral route is considered most natural, uncomplicated, convenient and safe due to its ease of administration, patient compliance and flexibility in formulation and cost effective manufacturing process [1]. Many of the drug delivery systems, available in the market are oral drug delivery type systems Pharmaceutical products designed for oral delivery are mainly immediate release type or conventional drug delivery systems, which are designed for immediate release of drug for rapid absorption. These immediate release dosage forms have some limitations such as:

1. Drugs with short half-life require frequent administration, which increases chances of missing dose of drug leading to poor patient compliance.
2. A typical peak-valley plasma concentration-time profile is obtained which makes attainment of steady state condition difficult.
3. The unavoidable fluctuations in the drug concentration may lead to under medication or overmedication as the C_{ss} values fall or rise beyond the therapeutic range.

4. The fluctuating drug levels may lead to precipitation of adverse effects especially of a drug with small therapeutic index, whenever overmedication occurs.[2]

In order to overcome the drawbacks of conventional drug delivery systems, several technical advancements have led to the development of controlled drug delivery system that could revolutionize method of medication and provide a number of therapeutic benefits.[3]

Controlled Drug Delivery Systems

Controlled drug delivery systems have been developed which are capable of controlling the rate of drug delivery, sustaining the duration of therapeutic activity and/or targeting the delivery of drug to a tissue.[4] Controlled drug delivery or modified drug delivery systems are divided into four categories.

1. Delayed release
2. Sustained release
3. Site-specific targeting
4. Receptor targeting

More precisely, controlled delivery can be defined as:-

1. Sustained drug action at a predetermined rate by maintaining a relatively constant, effective drug level in the body with concomitant minimization of undesirable side effects.
2. Localized drug action by spatial placement of a controlled release system adjacent to or in the diseased tissue.
3. Targeted drug action by using carriers or chemical derivatives to deliver drug to a particular target cell type.
4. Provide physiologically/therapeutically based drug release system. In other words, the amount and the rate of drug release are determined by the physiological/ therapeutic needs of the body.[5]

A controlled drug delivery system is usually designed to deliver the drug at particular rate. Safe and effective blood levels are maintained for a period as long as the system continues to deliver the drug (Figure 1).[6] Controlled drug deliveries usually results in substantially constant blood levels of the active ingredient as compared to the uncontrolled fluctuations observed when multiple doses of quick releasing conventional dosage forms are administered to a patient.

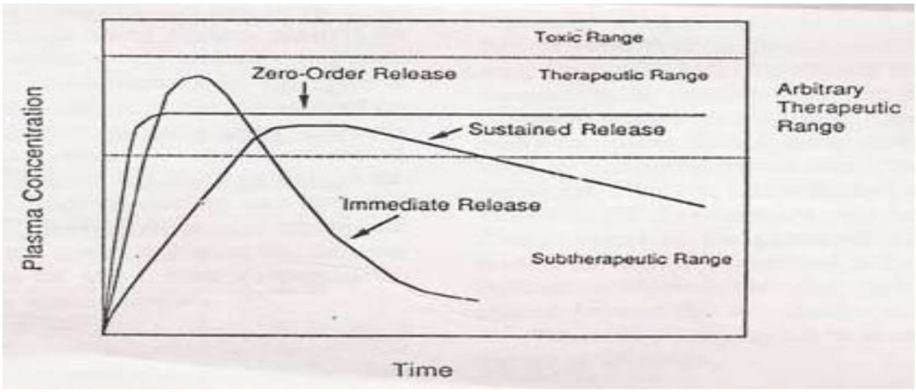

Fig 1: Drug level verses time profile showing differences between zero order, controlled releases, slow first order sustained release and release from conventional tablet

Oral drug delivery systems have progressed from immediate release to site-specific delivery over a period of time. Every patient would always like to have a ideal drug delivery system possessing the two main properties that are single dose or less frequent dosing for the whole duration of treatment and the dosage form must release active drug directly at the site of action.[7]

Thus the objective of the pharmacist is to develop systems that can be as ideal system as possible. Attempts to develop a single- dose therapy for the whole duration of treatment have focused attention on controlled or sustained release drug delivery systems. Attention has been focused particularly on orally administered sustained drug delivery systems because of the ease of the administration via the oral route as well as the ease and economy of manufacture of oral dosage forms. Sustained release describes the delivery of drug from the dosage forms over an extended period of time. It also implies delayed therapeutic action and sustained duration of therapeutic effect. Sustained release means not only prolonged duration of drug delivery and prolonged release, but also implies predictability and reproducibility of drug release kinetics. A number of different oral sustained drug delivery systems are based on different modes of operation and have been variously named, for example, as

dissolution controlled systems, diffusion controlled systems, ion-exchange resins, osomotically controlled systems, erodible matrix systems, pH- independent formulations, swelling controlled systems, and the like.

An orally administered controlled drug delivery system encounters a wide range of highly variable conditions, such as pH, agitation intensity, and composition of the gastrointestinal fluids as it passes down the G.I tract. Considerable efforts have been made to design oral controlled drug delivery systems that produce more predictable and increased bioavailability of drugs. However, the development process is precluded by several physiological difficulties, like inability to retain and localize the drug delivery system within desired regions of the G.I tract and highly variable nature of the gastric emptying process. An important factor, which may adversely affect the performance of an oral controlled drug delivery system, is the G.I transit time. The time for absorption in the G.I transit in humans, estimated to be 8-10 hr from mouth to colon, is relatively brief with considerable fluctuation. G.I transit times vary widely between individuals, and depend up on the physical properties of the object ingested and the physiological conditions of the gut. This variability may lead to predictable bioavaialability and times to achieve peak plasma levels. One of the important determinants of G.I transit is the residence time in the stomach.

Majority of the drugs are well absorbed from all the regions of the G.I tract while some are absorbed only from specific areas, principally due to their low permeability or solubility in the intestinal tract, their chemical instability, the binding of the drug to the gut contents, as well as to the degradation of the drug by the microorganisms present in the colon. Therefore, in instances where the drug is not absorbed uniformly over the G.I tract, the rate of drug absorption may not be constant in spite of the drug delivery system delivering the drugs at a constant rate into the G.I fluids. More particularly, in instances where a drug has a clear cut absorption window, i.e., the drug is absorbed only from specific regions of the stomach or upper parts of the small intestine; it may not be completely absorbed when administered in the form of a typical oral controlled drug delivery system. It is due to the relatively brief gastric emptying in humans, which normally averages 2-3 hrs through the major absorption zone. It may cause incomplete drug release from the dosage form at absorption sites leading to diminished efficacy of the administered dose. It is apparent that for a drug having such an absorption window, an effective oral controlled drug delivery system should be designed not only to deliver the drug at a controlled rate, but also to retain the drug in the stomach for a long period of time. For this drug, increased or more predictable availability would result if controlled release systems could be retained in the stomach for extended periods of time.

It is suggested that compounding narrow absorption window drugs in a unique pharmaceutical dosage form with gastro retentive properties would enable an extended absorption phase of these drugs. After oral administration, such a dosage form would be retained in the stomach and release the drug there in a controlled and prolonged manner, so that the drug could be supplied continuously to its absorption sites in the upper gastrointestinal tract. This mode of administration would best achieve the known pharmacokinetic and pharmacodynamic advantages of controlled release dosage form for these drugs.

Incorporation of the drug in a controlled release gastroretentive dosage form (CRGRDF) can yield significant therapeutic advantages due to a variety of pharmacokinetic and pharmacodynamic factors.

Controlled release or Extended-release dosage forms with prolonged residence times in the stomach are highly desirable for drugs.[8] which are

1. Administered two or more time a day.
2. Only absorbed in the upper GI regions.
3. Insoluble in water.
4. Targeted at sites in the upper GI tract.
5. Bioavailable through active transport mechanisms.
6. Irritating to the mucosa.
7. Misbalancing, irritating, or unsafe in the lower GI region.
8. More effective when plasma levels are more constant.
9. That is locally active in the stomach.
10. That has an absorption window in the stomach or in the upper small intestine.
11. That is unstable in the intestinal or colonic environment or degrades in colon.
12. Have low solubility at high pH values.

Biological aspects of gastric retention dosage forms

To comprehend the considerations taken in the design of gastric retention dosage forms and to evaluate their performance the relevant anatomy and physiology of the G.I tract must be fully understood. The extent of drug absorption in a segment of the G.I. tract depends generally on the rate of absorption as well as on the exposed surface area and time available for drug absorption. The G.I. Transit times of dosage forms in the various segments of the G.I. tract are listed in Table 1. The other factors influencing drug absorption are surface area, absorption mechanisms, pH values, enzymes and number of microorganisms.

Table 1: the Transit time of Different Dosage Forms across the Segments of GI Tract

Dosage form	Transit time (h)		
	Gastric	Small intestine	Total
Tablets	2.7±1.5	3.1±0.4	5.8
Pellets	1.2±1.3	3.4±1.0	4.6
Capsules	0.8±1.2	3.2±0.8	4.0
Oral solution	0.3±0.07	4.1±0.5	4.4

MATERIALS AND METHODS

Ofloxacin-Procured From Lupin Laboratory. Provided by SURA LABS, Dilsukhnagar, Hyderabad,HPMC K4M-Colorcon Asia Pvt. Limited, HPMC K15M-Colorcon Asia Pvt. Limited, HPMC K100M-Colorcon Asia Pvt. Limited, Lactose-Indchem International Ltd, Mumbai, India, NaHCO3-S.D. Fine Chemicals, Mumbai, India, MgS-S.D. Fine Chemicals, Mumbai, India, Talc-S.D. Fine Chemicals, Mumbai, India.

Methodology
Analytical method development
Determination of absorption maxima

A solution containing the concentration 10 µg/ mL drug was prepared in 0.1N HCL UV spectrum was taken using Double beam UV/VIS spectrophotometer. The solution was scanned in the range of 200 – 400 nm.

Preparation calibration curve

10mg Ofloxacin pure drug was dissolved in 10ml of methanol (stock solution1) from stock solution 1ml of solution was taken and made up with 10ml of 0.1N HCL (100µg/ml). From this 1ml was taken and made up with 10 ml of 0.1N HCL (10µg/ml). The above solution was subsequently diluted with 0.1N HCL to obtain series of dilutions Containing 2, 4, 6, 8, 10 µg /ml of per ml of solution. The absorbance of the above dilutions was measured at 285 nm by using UV-Spectrophotometer taking 0.1N HCL as blank. Then a graph was plotted by taking Concentration on X-Axis and Absorbance on Y-Axis which gives a straight line Linearity of standard curve was assessed from the square of correlation coefficient (R^2) which determined by least-square linear regression analysis.

Preformulation parameters

The quality of tablet, once formulated by rule, is generally dictated by the quality of physicochemical properties of blends. There are many formulations and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested as per Pharmacopoeia.

Angle of repose

The frictional force in a loose powder can be measured by the angle of repose. It is defined as, the maximum angle possible between the surface of the pile of the powder and the horizontal plane. If more powder is added to the pile, it slides down the sides of the pile until the mutual friction of the particles producing a surface angle, is in equilibrium with the gravitational force. The fixed funnel method was employed to measure the angle of repose. A funnel was secured with its tip at a given height (h), above a graph paper that is placed on a flat horizontal surface. The blend was carefully pored through the funnel until the apex of the conical pile just touches the tip of the funnel. The radius (r) of the base of the conical pile was measured. The angle of repose was calculated using the following formula:

$\tan \theta = h / r$ $\tan \theta$ = Angle of repose
h = Height of the cone , r = Radius of the cone base

Table 2: Angle of Repose values (as per USP)

Angle of Repose	Nature of Flow
<25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Bulk density

Density is defined as weight per unit volume. Bulk density, is defined as the mass of the powder divided by the bulk volume and is expressed as gm/cm^3. The bulk density of a powder primarily depends on particle size distribution, particle shape and the tendency of particles to adhere together. Bulk density is very important in the size of containers needed for handling, shipping, and storage of raw material and blend. It is also important in size blending equipment. 10 gm powder blend was sieved and introduced into a dry 20 ml cylinder, without compacting. The powder was carefully leveled without compacting and the unsettled apparent volume, Vo, was read.
The bulk density was calculated using the formula:
Bulk Density = M / V_o
Where, M = weight of sample
V_o = apparent volume of powder

Tapped density

After carrying out the procedure as given in the measurement of bulk density the cylinder containing the sample was tapped using a suitable mechanical tapped density tester that provides 100 drops per minute and this was repeated until difference between succeeding measurement is less than 2 % and then tapped volume, V measured, to the nearest graduated unit. The tapped density was calculated, in gm per L, using the formula:
Tap = M / V
Where, Tap= Tapped Density
M = Weight of sample
V= Tapped volume of powder

Measures of powder compressibility

The Compressibility Index (Carr's Index) is a measure of the propensity of a powder to be compressed. It is determined from the bulk and tapped densities. In theory, the less compressible a material the more flowable it is. As such, it is measures of the relative importance of interparticulate interactions. In a free- flowing powder, such interactions are generally less significant, and the bulk and tapped densities will be closer in value.

For poorer flowing materials, there are frequently greater interparticle interactions, and a greater difference between the bulk and tapped densities will be observed. These differences are reflected in the Compressibility Index which is calculated using the following formulas:
Carr's Index = [(tap - b) / tap] × 100
Where, b = Bulk Density
Tap = Tapped Density

Table 3: Carr's index value (as per USP)

Carr's index	Properties
5 – 15	Excellent
12 – 16	Good
18 – 21	Fair to Passable
2 – 35	Poor
33 – 38	Very Poor
>40	Very Very Poor

Formulation development of floating Tablets
Procedure for direct compression method

1) Drug and all other ingredients were individually passed through sieve no ≠ 60.
2) All the ingredients were mixed thoroughly by triturating up to 15 min.
3) The powder mixture was lubricated with talc.
4) The tablets were prepared by using direct compression method by using 8 mm punch.

Formulation of tablets

Table 4: Formulation composition for Floating tablets

INGREDIENTS	FORMULATION CODE											
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Ofloxacin	100	100	100	100	100	100	100	100	100	100	100	100
HPMC K4M	30	60	90	120	-	-	-	-	-	-	-	-
HPMC K15M	-	-	-	-	30	60	90	120	-	-	-	-

HPMC K100M	-	-	-	-	-	-	-	-	30	60	90	120
Lactose	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
NaHCO3	10	10	10	10	10	10	10	10	10	10	10	10
Magnesium stearate	5	5	5	5	5	5	5	5	5	5	5	5
Talc	3	3	3	3	3	3	3	3	3	3	3	3
Total Weight	300	300	300	300	300	300	300	300	300	300	300	300

All the quantities were in mg

RESULT AND DISCUSSION

Analytical Method

Determination of absorption maxima

The standard curve is based on the spectrophotometry. The maximum absorption was observed at 285 nm.

Calibration curve

Graphs of Ofloxacin was taken in 0.1N HCL (pH 1.2)

Table 5: Observations for graph of Ofloxacin in 0.1N HCl

Conc [µg/mL]	Abs
0	0
2	0.128
4	0.254
6	0.368
8	0.478
10	0.591

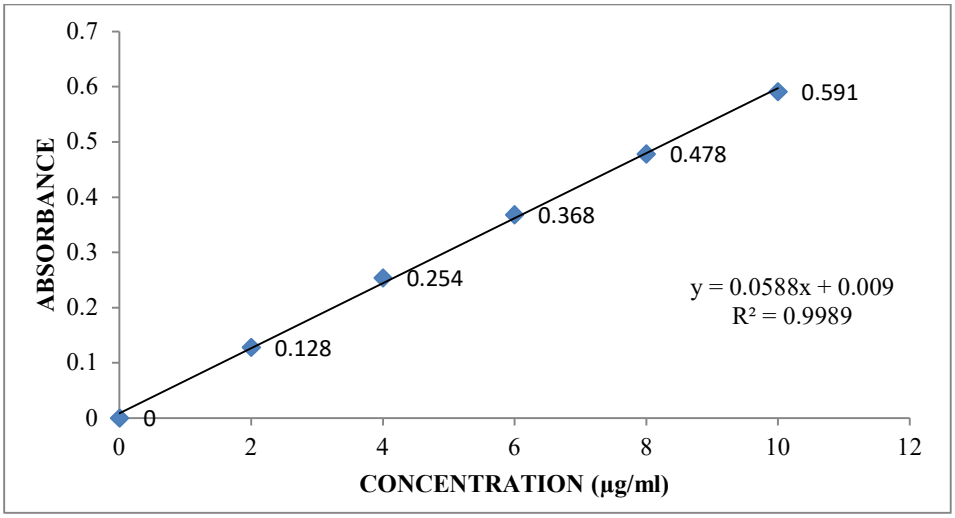

Fig 2: Standard graph of Ofloxacin in 0.1N HCL

Standard graph of Ofloxacin was plotted as per the procedure in experimental method and its linearity is shown in Table 8.1 and Fig 8.1. The standard graph of Ofloxacin showed good linearity with R^2 of 0.998, which indicates that it obeys "Beer- Lamberts" law.

Preformulation parameters of powder blend

Table 6: Pre-formulation parameters of blend

Formulation Code	Angle of Repose	Bulk density (gm/mL)	Tapped density (gm/mL)	Carr's index (%)	Hausner's Ratio
F1	29.73±0.02	0.449±0.05	0.518±0.06	13.32±0.02	1.15±0.03

F2	30.96±0.06	0.405±0.05	0.468±0.06	13.46±0.01	1.15±0.04
F3	32.01±0.04	0.409±0.04	0.478±0.07	14.43±0.02	1.16±0.02
F4	28.01± 0.04	0.469±0.04	0.525±0.08	10.66±0.02	1.11±0.03
F5	26.32 0.06	0.45±0.08	0.548±0.02	17.88±0.03	1.21±0.02
F6	27.07±0.02	0.471±0.04	0.569±0.02	17.22±0.02	1.20±0.04
F7	25.17±0.03	0.459±0.02	0.57±0.02	19.47±0.02	1.24±0.01
F8	29.98±0.01	0.458±0.01	0.54±0.011	15.18±0.02	1.17±0.03
F9	23.75 ±0.01	0.446±0.05	0.539±0.09	17.25±0.07	1.20±0.02
F10	28.1±0.03	0.461±0.08	0.539±0.09	14.47±0.01	1.16±0.04
F11	26.57±0.05	0.405±0.06	0.5±0.04	19±0.02	1.23±0.03
F12	28.07±0.02	0.418±0.01	0.505±0.02	17.22±0.08	1.20±0.01

Tablet powder blend was subjected to various pre-formulation parameters. The angle of repose values indicates that the powder blend has good flow properties. The bulk density of all the formulations was found to be in the range of 0.45±0.08 to 0.471±0.04 (gm/ml) showing that the powder has good flow properties. The tapped density of all the formulations was found to be in the range of 0.5±0.04 to 0.569±0.02 showing the powder has good flow properties. The compressibility index of all the formulations was found to be below 19.47 which show that the powder has good flow properties. All the formulations has shown the hausners ratio ranging between 1.11 to 1.24 indicating the powder has good flow properties.

Quality Control Parameters For tablets

Tablet quality control tests such as weight variation, hardness, and friability, thickness, Drug content and drug release studies were performed for floating tablets.

***In vitro* quality control parameters**

Formulation codes	Weight variation (mg)	Hardness (kg/cm^2)	Friability (%loss)	Thickness (mm)	Drug content (%)	Floating lag time(Sec)	Total Floating Time(Hrs)
F1	299.64	5.2	0.32	4.15	98.31	59	8
F2	298.32	5.9	0.43	4.96	97.28	62	10
F3	300.14	5.4	0.15	4.22	99.62	35	7
F4	297.98	5.1	0.68	4.35	98.55	46	12
F5	296.25	5.6	0.25	4.18	96.38	26	9
F6	300.05	5.7	0.11	4.39	95.89	19	7
F7	298.15	5.0	0.75	4.75	99.72	34	8
F8	297.90	5.9	0.29	4.39	97.19	20	12
F9	298.21	5.7	0.56	4.12	98.83	43	11
F10	299.83	5.2	0.41	4.82	99.25	56	12
F11	300.13	5.0	0.62	4.75	98.41	21	10
F12	299.68	5.6	0.32	4.21	97.68	62	9

All the parameters such as weight variation, friability, hardness, thickness, drug content were found to be within limits.

***In Vitro* Drug Release Studies**

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0	0	0	0	0	0	0	0	0	0	0	0	0
1	11.58	7.25	10.20	06.35	13.11	15.32	23.85	28.42	14.73	16.42	20.45	15.28
2	26.35	11.31	16.61	10.15	20.56	21.56	36.90	35.61	19.98	24.25	27.91	29.31
3	31.89	18.89	23.85	18.11	26.95	28.71	41.65	40.13	24.86	30.91	33.26	34.86
4	38.54	25.10	32.11	23.91	35.56	32.90	47.23	43.54	28.12	33.59	37.96	41.52
5	47.28	35.51	41.25	32.48	37.71	37.15	52.89	51.32	35.68	47.75	42.85	46.71
6	55.31	41.19	50.86	39.62	42.91	41.86	57.72	58.14	41.10	52.53	50.64	53.86
7	62.50	46.87	56.20	48.37	46.30	48.75	60.98	62.80	46.27	59.70	56.48	56.24
8	67.14	53.96	61.46	52.75	53.26	53.96	62.54	68.51	53.79	63.21	61.31	60.87
9	73.86	56.24	65.82	57.12	58.22	56.26	64.15	72.47	69.46	68.48	65.16	66.65
10	85.41	62.31	74.72	66.48	61.38	64.87	75.12	74.71	79.60	71.22	73.62	71.23
11	89.92	72.75	78.95	69.14	68.55	75.96	77.28	86.25	84.76	80.38	77.19	75.54

12	98.86	78.23	81.54	73.95	71.67	80.42	86.19	99.34	96.82	85.90	82.37	78.21

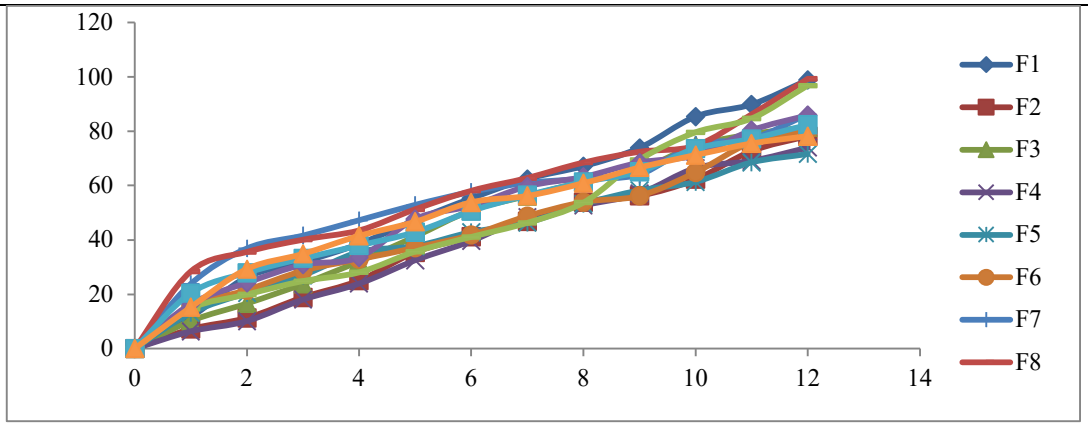

Fig 3: Dissolution data of Ofloxacin Floating tablets containing all formulations (HPMC K4M, HPMC K15M, and HPMC K100M)

From the dissolution data it was evident that the formulations prepared with HPMC K4M as polymer were retarded the drug release more than 12 hours. Hence from the above dissolution data it was concluded that F8 formulation was considered as optimised formulation because good drug release (99.34%) in 12 hours.

Application of Release Rate Kinetics to Dissolution Data for optimised formulation

Table 7: Application kinetics for optimised formulation

Cumulative (%) Release Q	Time (T)	Root (T)	Log(%) Release	Log (T)	Log (%) Remain	Release Rate (Cumulative % Release / T)	1/Cum% Release	Peppas Log Q/100	% Drug Remaining	Q01/3	Qt1/3	Q01/3-Qt1/3
0	0	0			2.000				100	4.642	4.642	0.000
28.42	1	1.000	1.454	0.000	1.855	28.420	0.0352	-0.546	71.58	4.642	4.152	0.490
35.61	2	1.414	1.552	0.301	1.809	17.805	0.0281	-0.448	64.39	4.642	4.008	0.633
40.13	3	1.732	1.603	0.477	1.777	13.377	0.0249	-0.397	59.87	4.642	3.912	0.730
43.54	4	2.000	1.639	0.602	1.752	10.885	0.0230	-0.361	56.46	4.642	3.836	0.805
51.32	5	2.236	1.710	0.699	1.687	10.264	0.0195	-0.290	48.68	4.642	3.651	0.990
58.14	6	2.449	1.764	0.778	1.622	9.690	0.0172	-0.236	41.86	4.642	3.472	1.169
62.8	7	2.646	1.798	0.845	1.571	8.971	0.0159	-0.202	37.2	4.642	3.338	1.303
68.51	8	2.828	1.836	0.903	1.498	8.564	0.0146	-0.164	31.49	4.642	3.158	1.484
72.47	9	3.000	1.860	0.954	1.440	8.052	0.0138	-0.140	27.53	4.642	3.020	1.622
74.71	10	3.162	1.873	1.000	1.403	7.471	0.0134	-0.127	25.29	4.642	2.935	1.706
86.25	11	3.317	1.936	1.041	1.138	7.841	0.0116	-0.064	13.75	4.642	2.396	2.246
99.34	12	3.464	1.997	1.079	-0.180	8.278	0.0101	-0.003	0.66	4.642	0.871	3.771

Drug – Excipient compatibility studies
Fourier Transform-Infrared Spectroscopy

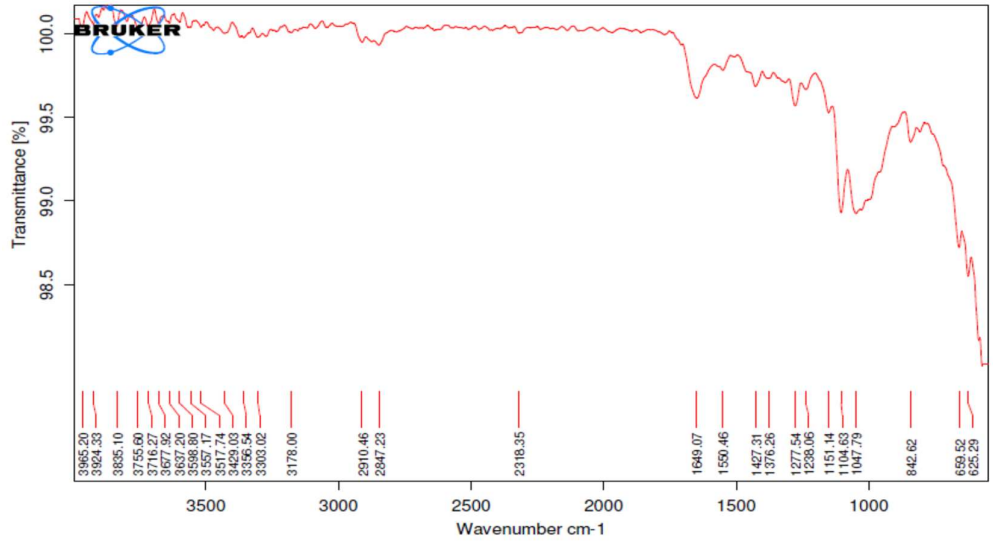

Fig 4: FTIR Spectrum of pure drug

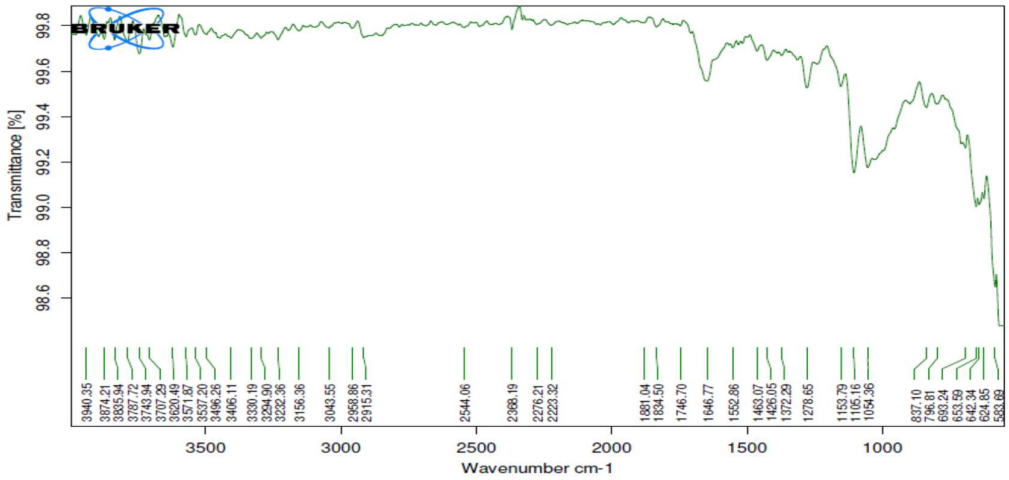

Fig 5: FTIR Spectrum of optimised formulation

There was no disappearance of any characteristics peak in the FTIR spectrum of drug and the polymers used. This shows that there is no chemical interaction between the drug and the polymers used. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions. Ofloxacin are also present in the physical mixture, which indicates that there is no interaction between drug and the polymers, which confirms the stability of the drug.

CONCLUSION

Over the years, various attempts have been made to control the time course of drug in the body through a variety of drug modifications and dosage forms. One of the most feasible approaches for achieving a prolonged and predictable drug delivery profile in the gastrointestinal tract is to control the GRT. The approach of the present study was to formulate floating tablets of Ofloxacin and hence for the evaluate the release profiles of these formulations. From the results obtained in the present study, the following conclusions are drawn:

- ✓ The IR spectrum of pure drug and drug-polymer mixture revealed that there was no interaction between polymer and drug. The prepared floating tablets are industrially feasible method.
- ✓ Bulk density and tapped density shown good packability, and Carr's index results shown excellent compressibility.
- ✓ Formulation F8 containing 120 mg of HPMC K15M was found to release a maximum of 99.34 % at the 12th hour.
- ✓ Comparison of all formulations of Ofloxacin revealed the fact that developed formulation F8 showed comparable release characteristics, and thus, it may have fair clinical efficacy. Hence, the formulation F8 has met the objectives of the present study.

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